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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,810	07/10/2001	Kevin R. Mc Intosh	640100-416	7470

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EXAMINER

EWOLDT, GERALD R

ART UNIT PAPER NUMBER

1644

DATE MAILED: 04/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,810

Applicant(s)

MC INTOSH ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/10/03, 10/06/03, 2/09/04.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
4a) Of the above claim(s) 3, 14, 15, 18, 23, 25, 29 and 33 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 2, 4-13, 16, 17, 19-22, 24, 26-28 and 30-32 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's elections with traverse of Group I, filed 10/06/03, and the species: bone marrow (tissue type) and allogeneic (fibroblast type) with traverse, filed 2/09/04, are acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the species restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claim 33 is withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention. Claims 3, 14, 15, 18, 23, 25, and 29 are withdrawn from further consideration by the Examiner as being drawn to nonelected species.

Claims 1, 2, 4-13, 16, 17, 19-22, 24, 26-28, and 30-32 are pending and under examination.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 4, 5, 8, 9, 11-13, 16, 17, 19, 21, 24, 26-28, 30, and 32 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Soiffer et al. (1997), as evidenced by U.S. Patent No. 5,736,396 (1998).

Soiffer et al. teaches a method of inducing a reduced immune response to donor tissue in a bone marrow transplant (BMT) recipient, or reducing an immune response against recipient tissue by donor tissue, or treating a transplant recipient for graft versus host disease, comprising treating (or contacting) the recipient with allogeneic (donor derived) fibroblasts and immunosuppressive agents (see particularly, page 3040, *Treatment protocol*). Note that the '396 patent merely establishes that bone marrow includes fibroblasts (see column 4, lines 41-45), thus, any BMT recipient would also receive donor derived fibroblasts. Further note that the phrase reciting "in an amount effective to reduce an immune response" does not comprise an actual limitation as no threshold amount of fibroblasts has been established, thus, the small number of fibroblasts in bone marrow

would reduce the immune response some small amount. Additionally, the intention of treatment, "to treat rejection" (Claim 11) also fails to comprise an actual limitation.

The reference clearly anticipates the claimed invention.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 6, 7, 10, 20, 22, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soiffer et al. in view of Donnelly et al. (1993, IDS).

Soiffer et al. has been discussed above.

The reference teaching differs from the claimed invention only in that it does not teach the use of fibroblasts allogeneic to both the transplant donor and the recipient nor does it teach various different times of administration of said fibroblasts, i.e., before, during, or after BMT.

Donnelly et al. teaches that fibroblasts are immunosuppressive, interfere with lymphocyte activation, and interfere with alloimmune responses (see particularly the abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform the BMT method of Soiffer et al. including additional fibroblasts. One of ordinary skill in the art at the time the invention was made would have been motivated to include said additional fibroblasts given the teachings of Donnelly et al. that fibroblasts are immunosuppressive, interfere with lymphocyte activation, and interfere with alloimmune responses. Note that as there are only 3 possible types/sources of fibroblasts, autologous to the recipient, autologous to the donor, or allogeneic to both, the choice of any convenient source would be obvious. Also note that the timing of administration, i.e., administration of the fibroblasts before, during, or after transplantation comprises only routine optimization that would

fall well within the purview of one of skill in the art at the time of the invention.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

Please Note: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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4/21/04
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